

Conference on Sham Neurosurgical Procedures in Clinical Trials NIH

Edmund D. Pellegrino, M.D.

Professor Emeritus of Medicine and Medical Ethics

Georgetown University

(No conflicts of interest)

Moral Agency

- Morals—beliefs about right and wrong
- Ethics—formal, critical, systematic study of right and wrong human acts
- Ethics begins when morals are challenged

“It is not easy to determine how one ought to become angered, with whom, and on what sort of grounding and for how long...it is not easy to declare in a rule (toi, logoi) by how and in what manner of variance a person becomes blameworthy. For the decision depends upon the particular facts and upon perception.”

(NE, 1126a, 32b4, also 1109, b 14-23)

Ethics a Practical Discipline

Best discussed in context of real world—concrete, existential detail recognizing Aristotle's caveat

But, without principle and precepts we are left with opinion and so called common sense

Science and ethics two individually valid realms—
Einstein's caveat:

Science tells us how things relate to each other in the material world: it cannot tell us what we should do.

Investigative Medicine

Ends: good of patient=good of subject
truth of experimental result

Investigator must serve both, good of human trumps expt.
Truth

Research policies, rules principles
protect patient, subject, truth comes through the person
of the investigator

Investigator and/or physician in charge is morally and
legally responsible if harm occurs

Therefore, character of investigator is the major protection of
good and truth

Character of the Investigator

In the end, all principles, rules, policies and moral judgment must be applied by a human being—the investigator who is the morally and legally responsible agent who must make the prudent decision—just as the attending physician in therapeutic medicine.

Conflicts of Interest

“Any personal interest in an outcome, institution, or entity that is at odds with the person’s professional obligations should be avoided.”

Beauchamp and Childress, p. 324

A conflict of interest is a set of circumstances that create a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

IOM 2010

Some Special Ethical Issues in Neurodegenerative Disease

- Use of human fetal/embryonic tissue transplants (no acceptable compromise)
- Special vulnerability of patient vis a vis valid consent
- Evaluation of therapeutic and sham effects given natural history of the disease
- Investigator, treating physician must not be the same
- Robust project oversight committee
- Unrealistic public expectations of research, biotechnology



When facts, outcome and ethics are unclear and action must be taken:

- Prudential decision making—prudence a moral and intellectual virtue
- Not excessive caution, face saving, avoid risk of exposure or responsibility
- Instead, prudence as a virtue is practical wisdom—a habitual capacity to make the best decision (right and good) in the face of uncertainty
- The mark of the mature clinician



Prudence uses the precautionary principle: not simple benefit/harm algebra, includes moral harm in the equation



Value of this conference:
interdisciplinary statement of
questions needed, close dialectic
beyond dialogue to arrive at practice
guidelines